

RESEARCH PROTECTIONS UPDATE

News and Comment on the Protection of Human Subjects in Navy and Marine Corps Research

Vol. 5 Number 2

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SPRING 2014

Comment

The Social-Behavioral Context

“Social-behavioral” research is a comprehensive term that is intended to encompass many directions in research, including Navy research, that involve human subjects.

More authoritatively, *Institutional Review Board Management and Function*, a widely used reference on human protection policy, suggests that “social science is the study of human society and of individual relationships in, and to, society.”

What does that mean for Navy human research protections? Apart from medical research (covered in our Winter issue), it means nearly everything.

Dr. Tim Singer, just-retired director of ONR’s Research Protections Division, who chaired the original DON HRPP Working Group in 2005 and led early battles to explain its mission, composed the following:

“The DON HRPP reconciles the competing priorities of conducting potentially risky work involving human subjects and compliance with federal, DoD, and DON policies intended to protect the safety and welfare of human subjects.”

He added that “this research includes development of improved diving apparatus and techniques; human performance testing under environmental and workload stress; and development, testing/evaluation

of personal protective equipment.”

Social-behavioral research also encompasses work on training methodologies, human and machine integration for combat systems, educational testing, modeling and simulation for team operations, and surveys of personnel.

Applying the concept further, social-behavioral research for the DON may include protocols that could contribute to development of fleet operational doctrine and tactical concepts, but also new technologies and weapon systems, and supporting processes and procedures.

One example of such work would be the development, now underway in several Navy and industry labs, of autonomous land vehicles capable of tactical decision-making to support Marine Corps or Army squads and platoons, using advanced sensors and processors for navigation and firing calculations.

Such systems, when fielded, will operate essentially as living members of the units to which they are attached, multiplying combat power while minimizing risk to personnel.

The Services have used unmanned systems for years for many missions, including surveillance, intelligence collection, and ordnance delivery and disposal. In the very near future, development of artificial intelligence

software will enable those systems also to replicate and replace human decision-making, including decisions with authentic ethical dimensions.

Such advances require a deep understanding of the complexities and subtleties of the human mind, which is the essence of social-behavioral science.

This pervasive social-behavioral context does much to clarify and reinforce the DON HRPP mission. If the work is Navy social-behavioral research, it must be addressed and guided by DON HRPP policy and practices.

The medical domain remains the province of the Military Treatment Facilities and the clinics. Everything else—the social-behavioral realm—defines what we do, and why we exist.

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Enriching Lives Through Research

By CAPT William Deniston

“Social-behavioral” research, as the terms suggests, addresses how humans act, either singly or in groups and, for Department of Navy work, typically in relation to established policies and programs. In some important ways it also encompasses non-formal, but generally accepted practices and customs of DON Commands and institutions.

If this seems a bit obscure, read our coverage of the fascinating research carried out by the Marine Corps University's Center for Advanced Operational Culture Learning (CAOCL) on the concept of “resilience” as a means for Marines to achieve balance between their commitment to the Corps and other areas of their lives.

Next, check our piece on work by Dr. Nita Lewis Shattuck of the Naval Postgraduate School (page 6) on the critical importance of sleep for ships' crews.

For the CAOCL effort, researchers led by Dr. Frank Tortorello explore the Marine Corps' long-accepted demand that Marines demonstrate total commitment not only to the Corps, but also to family and other life obligations.

The problem, Tortorello points out, is that, short of earning the Medal of Honor or Navy Cross,

“there's no such thing”; all commitment involves some degree of compromise. Attempting to be “totally” committed in all areas, he says, leads to severe personal stress. While the Corps ably trains Marines to be resilient in the face of combat, it does not adequately train them to deal with other challenges of life, Tortorello says.

Finding ways to do so, he adds, requires a better understanding of how Marines measure and come to terms with their own values and priorities.

Dr. Shattuck identifies a specific policy direction, the now-abandoned “Optimal Manning” experiment for the fleet, and documents the consequences of it. Her extensive research on sleep deprivation aboard ship teaches important lessons about how policy must recognize and allow for basic human needs—the need for adequate sleep, among others.

These examples reveal the near-limitless scope of social-behavioral research and its importance for DON. It's our mission, at DON HRPP, to ensure these and other research efforts are properly conducted to help the Navy and Marine Corps reap the critically important benefits they offer.

DON HRPP Director Deniston Promoted to Captain

DON HRPP Director CDR William Deniston was promoted to Captain in March, in a small private ceremony at the National Archives while standing next to the United States Constitution, the document he swore to uphold and defend.

“My goal for DON HRPP is to protect human subjects in DON-supported and -conducted research. I believe this can best be accomplished by ensuring Institutional Officials, researchers, and those who support human subject research (HSR) know and understand the rules they agree to follow,” Deniston said.

“The DON HRPP is here to serve as a positive resource for Navy Commands and extramural performers who support and conduct HSR. We want

to help them comply with Navy policy on protecting human subjects, so they do not jeopardize their ability to perform their missions.”

Deniston, a native of Carbondale, Ill., was commissioned in December 1996 and earned his Ph.D. in experimental psychology at Southern Illinois University in 1997.

His first Navy assignment, at the Naval Health Research Center starting in 1997, led to his appointment in 2000 as Program Manager for NHRC's Field Medical Technologies Dept.

Following his NHRC tour he reported to Space and Naval Warfare Systems Center-San Diego (now Pacific), working in the Intelligence, Surveillance,

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Marine Corps University

Resilience and the Marines: Focusing on a “Way of Being”

The Center for Advanced Operational Culture Learning (CAOCL) at Marine Corps University, in support of the Marine Corps Commandant’s 2010 Planning Guidance, completed the first stage of an extensive two-part study intended to help the Corps understand the meaning and value of “resilience” in the lives of Marines, both enlisted and commissioned. The study reflects the views only of the researchers themselves.

The study team now is working to help Marine Corps organizations incorporate the results.

Dr. Kerry Fosher, Director of Research for the Translational Research Group (TRG) of CAOCL, who acted as principal investigator for the study says that the work, led by Dr. Frank Tortorello, a researcher for Professional Solutions who supports the TRG, explored the socio-cultural aspects of resilience, complementing research underway on the biomedical and psychological aspects of it.



Camp Pendleton Marines receive a safety brief before annual rifle qualification. USMC/S. STARR

Tortorello says that CAOCL asked the TRG to conduct the study in order to contribute the group’s expertise in social science for development of a clearer understanding of resilience—a key priority of the CMC guidance.

The initial effort, he says, consisted of two parts: first, a quantitative examination of the language used in the formal documents at the Corps’ Officer Candidate School at Quantico, Va., and second, a six-month study of OCS instructors and Marine

officer candidates, and drill instructors and recruits at Marine Corps Recruit Depot, Parris Island, S.C.

The document analysis, Tortorello explains, reveals “how Marines view themselves and how the Corps views them”: that is, as “responsible for a set of duties and obligations, which then form the basis for potential stress and resilience.”

He says that, for example, documentation referring to individuals as “recruits” positions future Marines as responsible for a host of obligations, but does not necessarily acknowledge responsibilities beyond the Corps.



Marines maneuver combat raiding craft in water-mobility training at Camp Schwab, Okinawa. USMC/A. TECH

By way of example, Tortorello points out that a long-standing critique of the medical profession is that doctors often are perceived as treating their patients not as people, but as their diseases.

Similarly, prison inmates often are treated simply as numbers. “This also is a critique of government, if the point is to realistically address issues of stress and resilience,” he adds.

The executive summary of the CAOCL “Resilience Research Project,” conducted through late 2012, suggests that “the primary existential commitment for Marines—what they live and die for—is the Corps and other Marines. The Corps would like all Marines to be absolutely steadfast in this commitment.”

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Marine Corps University

Resilience for the Corps: “Meaning and Values”

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The summary continues that Marines are taught concepts and strategies for being “flexible,” but practically speaking, these are directed toward maintaining steadfastness in their commitment to the Corps.

Tortorello says that the series of interviews reinforced Marines’ understanding of the Corps’ demand for total commitment both to the Marine Corps and in other areas of life, such as marriage and parenthood.



Lieut. Gen. Richard Tryon, CG, Marines Forces Command and Marine Corps Forces Europe, talks with Marines of the Black Sea Rotational Force 14 at Mihail Kogalniceanu Air Base, Romania. USMC/S.W. WHITING

“The problem is that there’s no such thing,” he says. “There are only a few instances of total commitment, and those get you a Medal of Honor or a Navy Cross—pure examples of self-sacrifice. Anything short of that involves some degree of compromise.”

Tortorello says that the interviews also revealed that many Marines, in attempting to achieve total commitment to the Corps and to other obligations, experience severe personal stress, as they try to “find a way forward among these competing value commitments.”

He points out, though, that the Navy and the Corps recognize stress primarily as a physical condition, measurable for example by levels of the

hormone cortisol in the pituitary and adrenal systems.

“Our study asks ‘what about these other forms of stress?’” Tortorello says.

He notes that the Marine Corps provides extensive training for Marines in dealing with the stress they experience in operations, such as how to fight and maneuver in combat. The Navy-Marine Corps official doctrine is found in Marine Corps Reference Publication 6-11c, *Combat Operational Stress Control (COSC)*, and in the Operational Stress Control and Readiness (OSCAR) program.

“Corps training teaches Marines how to be resilient in such situations—how to respond to and fight through ambushes, for example.

“The Corps tells the Marine: here’s the stressor, this is how you work through it, as long as the topic is combat and operations.”

Tortorello also cites an example of a “novel stressor”—a Marine recruit in boot camp being screamed at by a drill instructor or forced to make and remake his rack multiple times.

“As he gets used to it, day after day, he realizes that it’s not under his control. He thinks, O.K., I’m being yelled at, I just need to stand here, eyes forward.

“This is the new conceptualization. We’re saying that none of this is automated—not represented by cortisol levels in the blood—it’s actually an accomplishment by each and every Marine,” he says.

One of the key assumptions of the study is that “stress and resilience are ways of being, not physiological processes or psychological traits, although they may entail both physical and psychological considerations.”

A second assumption, building on the first, is that “what counts as stress, resilience, and steadfastness is primarily a matter of how Marines conceive of their way of life.”

Of course, some Marines find being yelled at

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Marine Corps University**Resilience: “Meaning and Values ...”**

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highly stressful. The study points out that “one Marine’s stressor is another Marine’s ‘easy day,’ because each holds a different conception of what counts as stress.”

Tortorello points out that despite the rigorous training the Corps provides in how to be resilient in intense combat environments, that training may not address all possible combat-related experiences—for example, dealing with a subordinate who for some reason fails to perform as directed.

Resolving that situation requires a type of resilience based more on an understanding of human behavior than tactics. Yet the problem “definitely impacts” combat effectiveness, he says.

Tortorello explains that “we’re talking about meaning, and values, and cultural practices, ways of looking at life, and deciding whether I want to be stressed today or do I want to be resilient.

“It’s not that Marines are philosophical when they get up in the morning, saying, ‘what kind of a person do I want to be today?’ But there are models of Marines who say to their Marines and others, you can make every day what you want it to be.

“Our ultimate point is: why not take that model and apply it to all these other situations that the Marine Corps never gives any instruction in?”

The report makes eight recommendations, some wide-ranging and others specific to training:

(1) Address the tension between steadfastness and

flexibility by developing models and content for judgment training. (2) Train the trainers to “raise the issue of preparing for non-combat stressors and those not related to their military occupational specialties by sharing their judgment and experience.

(3) Institutionalize support for resilience work, perhaps by referring Marines to helpful books, articles, and talks. (4) Give Marines a vocabulary and conceptual “toolbox” for dealing with stress, in order to teach Marines what counts as good judgment and how, when, and why to apply it, from core training to non-combat-related situations.

(5) Put it in writing by amending key doctrinal publications to clarify the Corps’ stance on resilience. (6) Reinvigorate the priority of face-to-face Marine interactions through mentoring and peer-to-peer guidance.

(7) Use previous cultural change as a template by drawing on past experience in refining Marine Corps culture. (8) Expand research to include families in order to help Marines engage their sense of worth among families and civilians.

Tortorello says that CAOCL is studying ways to integrate the lessons learned into curricula and training. He adds that the COSC and OSCAR doctrines currently are a “done deal”—the CAOCL study represents an alternative approach. Changing what is in place, he adds, is a “tough call.”

Education & Training: Guarding Against Data Breach

Breach of confidentiality, a risk associated with social-behavioral research, occurs when researchers divulge information about research participants without their permission. It can happen when researchers share data; through data theft; when researchers are careless about data storage; or when the identity of individual subjects can be determined.

Researchers and IRBs can protect participant

confidentiality by taking certain steps. The IRB review should examine the researcher’s provisions to protect the privacy of subjects and to maintain confidentiality of data.

The provisions can include a data protection plan that discusses data storage, encryption, removing or destroying subject identifiers when no longer needed, limiting data access, and educating

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Naval Postgraduate School

Shattuck: Passionate Advocate for Improving Sailors' Lives

"Sailors standing a 'five and dime' watch schedule aboard Navy ships are on watch for five hours, then have the next ten hours for their regular work assignments, meals, training, drills—and sleep," says Dr. Nita Lewis Shattuck of the Naval Postgraduate School.



A crewman aboard the destroyer McCampbell (DDG-85) stands a watch. USN/C. CAVAGNARO

"Their schedules don't allow them to sleep and work at the same time each day to maintain a 24-hour day. So in addition to having people work too many hours, we're also interfering with their bodies' natural circadian rhythms."

Shattuck, an associate professor in the Operations Research Department's Human Systems Integration program at NPS, is a passionate advocate for improving sailors' lives by letting them get a decent night's rest. And rest is one thing, she says, they don't get aboard many Navy ships.

"My mission is to get sailors better sleep—whether by changing their watch schedules, berthing spaces, or the mattresses they sleep on—whatever impedes sleep is what I'm trying to address," she says.

Shattuck has the facts to back up her passion. She has been conducting research in human performance for the military her entire 30-year career.

Since the early 2000s, she has looked closely at sleep patterns of Navy personnel and found what she calls an "appalling" pattern of sleep depri-

vation and fatigue—which, she explains, leads not only to decreased alertness and poor work performance, but also to memory issues, problems with morale, and high levels of stress, which result in an increased risk of psychiatric disorders and suicide.

Shattuck says she first learned of widespread sleep deprivation from her Navy and Marine Corps students, who told her that—unlike the Navy's aviation community, which enforces strict crew rest policies—ship crews do not get adequate rest.

She explains that following 9/11, as the Navy experienced a huge increase in optempo at the start of Operations Enduring Freedom and Iraqi Freedom, she received a call from a Navy senior medical officer asking for help with complaints about sleep deprivation from his ship's crew. He was aboard a deployed aircraft carrier teamed for round-the-clock operations with another carrier; his ship was assigned the night shift.

What followed was her first study of sleep patterns for the Navy. She says she found high levels of sleep deprivation, with crew members accruing a massive sleep debt over the course of a deployment.

She then conducted a study of sleep at the Navy's Recruit Training Command, Great Lakes, Ill. She found that the recruits, mostly young adults who need between 8.5 and nine hours of sleep each night, were allowed to get only six hours per night. After Shattuck's team's briefing, the Great Lakes commanding officer directed that recruits be allowed to get eight hours of sleep per night. Recruit test scores then improved dramatically.

"Navy recruits were being inculcated with a culture of sleep deprivation from day one," she says.

She then conducted a four-year longitudinal study of the sleep patterns of cadets at the U.S. Military Academy at West Point. Her study—the largest longitudinal study of sleep ever conducted—found that the cadets were getting about five hours

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*Naval Postgraduate School**Confronting the Dangers of Sleep Deprivation*

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of sleep per night—severe sleep deprivation. She compared the cadets' sleep patterns with sleep of students at Brown University and found that they got, on average, two hours less sleep per night than the Brown students.

Shattuck explains that the “culture of sleep deprivation and sleep restriction is almost a badge of honor in the Services.”

She points out that the Navy's Optimal Manning initiative, begun in 2001 in an attempt to reduce shipboard manning, led to severe reductions in sleep for ship crews.

“Fewer sailors were doing the same amount of work. They were over-tasked, and often so fatigued they could not be effective,” she says.

Optimal Manning was terminated in early 2011 following the release in 2010 of the Balisle Report, produced by a panel commissioned by ADM John Harvey, then Commander, Fleet Forces Command, to assess the state of the surface force. The report by the panel, chaired by retired VADM Phillip Balisle, strongly criticized the Navy's focus on reducing manning and funding for training and maintenance.

“Sailors ... were over-tasked and often so fatigued they could not be effective.”

“Thank goodness they came out with the report,” Shattuck says.

Shattuck's early research on fleet manning coincided with the period Optimal Manning was in effect. During that time, her team examined sleep patterns on five cruisers, destroyers and frigates, two submarines, one aircraft carrier, as well as a high-speed vessel.

“We went aboard ships and had the sailors wear sleep watches to document their sleep and activities.

“We then compared their activities to the Navy's standard work week, which at the time, specified that sailors are allowed eight out of every 24 hours to sleep. The Navy standard work week also limited sailors' work time to 72 hours per week. We found

that sailors were working many more hours than specified in the standard work week—and much of it was at the cost of sleep.”

In 2010 Shattuck was part of an interdisciplinary research team funded by the Office of Naval Research as part of an effort led by ONR's Warfighter Performance Department that looked at the effects of motion, heat, and sleep deprivation on human performance. With ONR support she collected data on the first two littoral combat ships, *Freedom* (LCS-1) and *Independence* (LCS-2).

Shattuck has continued her research aboard two destroyers, a carrier, and *Independence*. She discovered that crews were subjected to an “amazingly ill-advised” practice of being assigned to work on non-circadian schedules, meaning their “day” was other than 24 hours in length. Work and watchstanding assignments did not allow for sleeping and working the same time each day.

“Instead, their days were inconsistent with most sailors working an 18- or 20-hour day, or even a 15-hour day—the ‘five and dime,’” she says.

“So in addition to having people work way too much, we're also interfering with their natural circadian rhythms. The sleep they get isn't as beneficial as it could be if they were sleeping the same time each day. Submariners work an 18-hour day, which means every 18 hours it's morning—the equivalent of flying to Europe from the east coast every day. That's a whole lot of jet leg”

“Some people are less vulnerable to jet lag, but it takes a toll on everyone at some level. The ‘five and dime’ schedule drains sailors of energy and fatigues them unnecessarily.”

Shattuck has found that if the personnel are available, a three- or four-section circadian watch allows crews more sleep of better quality. If crews are too small, even the “port and starboard” schedule of six hours on and six hours off is more compatible with human circadian rhythms, because the sailors would be sleeping and working on the 24-hour clock.

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*Naval Postgraduate School****“The Number of Sailors is Critical ...”****(Continued from page 7)*

Still, that’s still not much time off, she says, adding that personnel who stand watch in the ship’s combat information center must be alert enough for their entire watch to monitor radar systems for potential hostile target tracks.

“Unless they’re given time for napping or have no other responsibilities when they are off watch, they’re going to be very fatigued,” she says.

Recently, Shattuck completed a study for the Office of the Chief of Naval Operations on notional manning levels of 40, 50, and 60 personnel for LCS.

“The number of sailors is critical. If you don’t get the number correct, people will suffer as a result.”

Shattuck went to sea aboard *Independence* for rough-water trials in February. She observed that mild motion sickness caused by rough water can induce drowsiness—a condition called “sopite syndrome,” and actually help sailors sleep. But severe motion degrades sleep quality. While the LCS is designed to operate in littoral, rather than

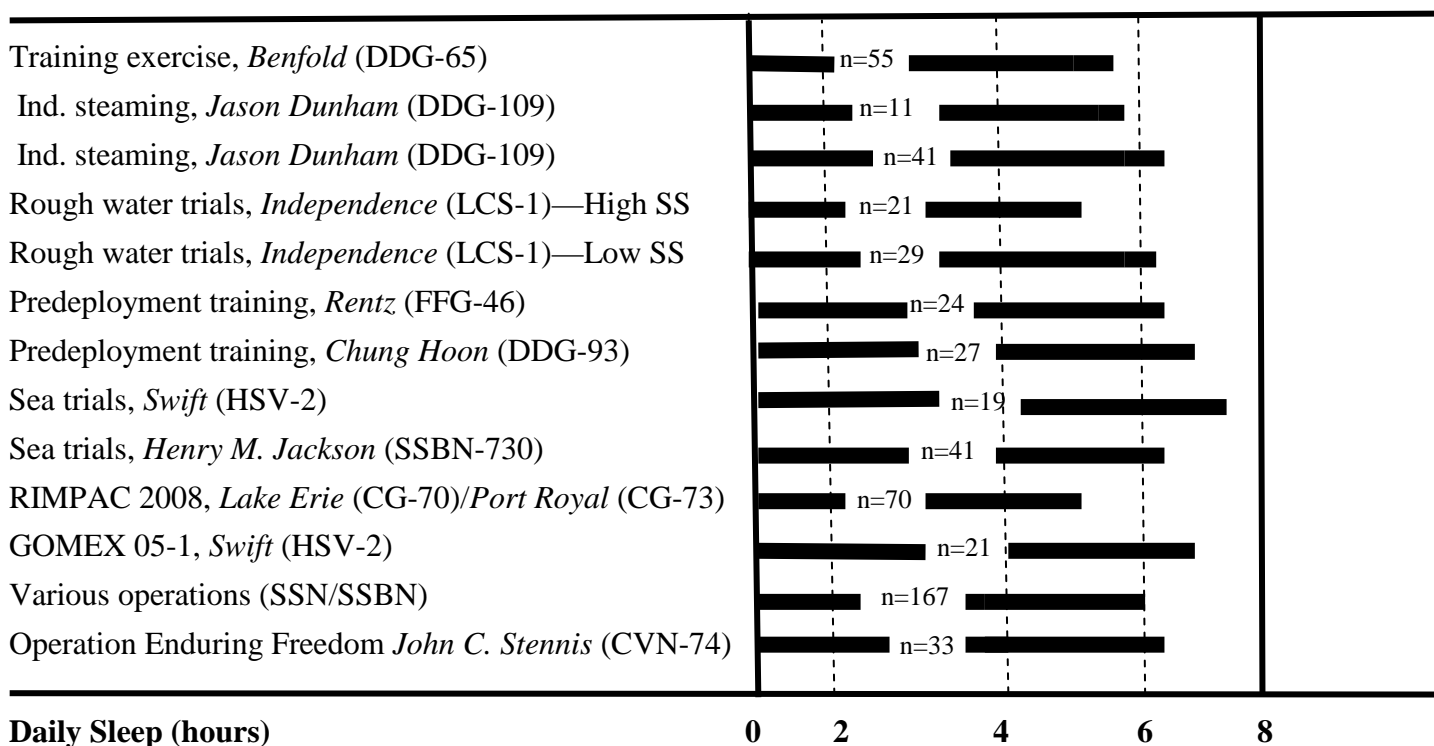
heavy seas, the trials produced useful data.

She cites the consequences the Navy faces by not manning ships adequately: accidents and increased stress that take an emotional and physical toll.

“We have this huge population of ‘shift workers’ in the Navy,” she says, noting that the sleep of shift workers is affected into retirement—and may cause a phenomenon known as “circadian scarring.”

Shattuck notes that she has met some resistance to giving sailors better sleep and work patterns, but also sees a groundswell of support. “Probably eight or 10 ships are trying out a ‘3/9’ circadian watch schedule right now,” she says. “The Naval Safety Center has been very supportive in getting the word out about the importance of adequate rest.”

She says that the 3/9 gives individuals adequate time off so they can get a full night’s sleep. The 3/9 schedule can be rotated every few weeks, but another advantage is that it allows watch crews to develop a rhythm, building team cohesion, she adds.

NPS SLEEP STUDIES – NAVAL OPERATIONS 2002-2013

Deniston Promoted to Captain

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and Reconnaissance Dept. He later was named co-lead for Command performance improvement.

In October 2004 LCDR Deniston reported to the Office of Naval Research (ONR) as Deputy Director of the Neural, Cognitive, and Social S&T Division.

In January 2005, following the standup of the DON Human Research Protection Working Group, Deniston was named Deputy for the group, which was directed to develop the DON HRPP.



CAPT Deniston with wife Leah, son Jake

In that role, he worked with Dr. Tim Singer, Working Group director, and CAPT Eileen Villasante, the first DON HRPP director, and two contract support staff (Ms. Marianne Elliott and Mr. Edward Walsh) to draft SECNAVINST 3900.39D, which established the DON HRPP. He conducted extensive briefings on the DON HRPP mission for

DON officials, visited DON Commands nationwide, and briefed joint-service HRPP managers at the first DoD HRPP Training Day in 2007. He served as the Deputy Director of ONR's newly formed Research Protections Division.

Deniston reported to the Bureau of Medicine and Surgery in September 2007 as Deputy, DON HRPP, and was promoted to Commander in August 2008. He traveled worldwide providing oversight and monitoring to DON Commands that conduct HSR.

From January 2010 to December 2012 he served as Assistant for Command Climate Evaluation at the Office of the Naval Inspector General. In that role, he acted as the voice of DON civilians and military personnel, ensuring their concerns and issues were presented to the Secretary of the Navy and Chief of Naval Operations.

In January 2013 he was named Program Manager for Deployment Mental Health Research in the Wounded, Ill & Injured (WII) program, BUMED. He also served as the Director of Strategic Integration for the WII program. He returned to the DON HRPP as interim Director in late 2013 and was formally assigned as Director last month.

"Naval researchers need to know that they have an obligation to protect human subjects, because it's good leadership, and the law," he said.

"As we increase awareness in the research activities, we want to help them comply with the law so they can carry out their important missions."

Protecting Data *(Continued from page 5)*

staff about the need to guard data.

Additional protections could include a waiver of documentation of consent if the consent signature is the only record linking the subject and the data; collecting the minimum number of subject identifiers; and, if collecting data electronically,

using secure modes of transmission.

Researchers also must inform participants of the limits of confidentiality. One of the basic elements of consent requires a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

RESEARCH PROTECTIONS UPDATE is published by the Department of the Navy Human Research Protection Program. Email: human.research@med.navy.mil, phone: 703-681-9629. CAPT William Deniston, publisher, Patti Yasenchak, editor, email patricia.yasenchak@navy.mil, phone 703-696-2864, Ed Walsh, managing editor. Material appearing in **RESEARCH PROTECTIONS UPDATE** is not copyrighted and may be redistributed in electronic or printed form.